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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,674	02/28/2002	Johannes Bartholomaeus	148/50986	2545
23911	7590	08/04/2005	EXAMINER OH, SIMON J	
CROWELL & MORING LLP INTELLECTUAL PROPERTY GROUP P.O. BOX 14300 WASHINGTON, DC 20044-4300			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 08/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/084,674	Applicant(s) BARTHOLOMAEUS ET AL.	
	Examiner Simon J. Oh	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2004.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-67 is/are pending in the application.
4a) Of the above claim(s) 10,13,14,16,19,20,22-29,33-54 and 59-61 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1,3-9,11,12,15,17,18,21,30-32 and 55-58 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment and response, both received on 17 February 2004. Receipt is acknowledged of the applicant's declaration, submitted under 37 C.F.R. § 1.132.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-67 under 35 U.S.C. 112, first paragraph, for enablement, is maintained.

The rejection of Claims 11 and 12 under 35 U.S.C., second paragraph, is hereby withdrawn in view of the amendments to those claims.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3-9, 11, 12, 15, 17, 18, 21, 30-32, and 55-58 rejected under 35 U.S.C. 103(a) as being unpatentable over Oshlack *et al.* (PCT Publication No. WO 99/01111) in view of Sackler *et al.* (U.S. Patent No. 5,478,577)

The Oshlack *et al.* reference discloses a stabilized sustained release solid oral dosage form, which includes an effective amount of tramadol or a pharmaceutically acceptable salt thereof, dispersed in a material of a hydrophobic material (See Abstract). Suitable pharmaceutically

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acceptable salts of tramadol for use are those conventionally known in the art, such as pharmaceutically acceptable acid addition salts (See Page 11, Lines 3-5). Although tramadol hydrochloride is specifically mentioned, the reference suggests the use of other, or tramadol HCL would be the only salt discussed throughout the specification. The reference also teaches that the sustained release matrix includes a hydrophobic polymer that comprises one or more alkylcelluloses, particularly ethylcellulose (See Page 15, Lines 13-16). Additionally, the reference teaches that the sustained release preparation can be presented as granules, multi-particulates, capsules, or preferably tablets (See Page 176, Lines 22-23). Furthermore, tablets may be covered with a hydrophobic polymer film coating, such as an acrylic polymer, including but not limited to acrylic acid and methacrylic acid copolymers (See Page 18, Lines 14-17).

The Oshlack *et al.* reference does not explicitly disclose the use of mixtures of salts of tramadol.

The Sackler *et al.* reference is used here as a teaching reference, merely to show that the use of mixtures of salts of tramadol has been contemplated by the prior art (See Column 6, Line 62 to Column 7, Line 16).

One of ordinary skill in the art would be motivated to combine the prior art references in order to make obvious the instantly claimed invention, as both references disclose differential release formulations comprising tramadol and its salts. As such, they are analogous art, and according to *In re Kerkhoven*, 205 USPQ 1069, 1072 (CCPA- 1980), "It is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. As this court explained in *Crockett*, 126 USPQ 186, 188 (CCPA- 1960), the idea of combining them flows logically from their

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having been individually taught in the prior art. Therefore, one of ordinary skill in the art can combine the prior art references with a reasonable expectation of success.

Although Oshlack et al. do not specifically teach the particular enteric coating claimed by the applicant, the reference does suggest the use of film coatings in general, particularly acrylate and methacrylate copolymers, which are known in the art to be enteric. Absent evidence to the contrary, it has not been made clear what sort of unexpected result would arise from the selection of a specific enteric coating. The selection of a known material based on its suitability for its intended use is obvious, absent a clear showing of unexpected results attributable to the applicant's specific selection.

Furthermore, it is the position of the examiner that one of ordinary skill in the art, at the time the instantly claimed invention was made, would have been aware of the of the individual solubility and bioavailability properties of different salts of the same active agent. Thus, in order to create a desired release profile of the active agent, the selection of a plurality of differing forms of the same drug is considered by the examiner to be within the purview of one of ordinary skill in the art. Hence, the instantly claimed invention is *prima facie* obvious.

Response to Arguments

Applicant's arguments with respect to the prior art rejection of Claims 1, 3-9, 11, 12, 15, 17, 18, 21, 30-32, and 55-58 have been considered but are moot in view of the new grounds of rejection.

Regarding the enablement rejection of record, the basis of the examiner's rejection of these claims was due to the breadth and scope of what sort of active agents are suitable for use in the instantly claimed invention. Although salt formation of an active agent may not be unpredictable, the bioavailability of a particular salt, particularly in conjunction with another salt of the same active

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agent, as recited in the instant claims, cannot be known without painstaking and undue experimental study. More to the point, the applicant has not shown that the instantly claimed invention will function as intended for each and every drug that is claimed, whether recited by name, or merely described by its general function. Furthermore, the applicant has not shown that the instantly claimed invention will function for each and every drug encompassed by the claims in a manner that is attributable to the recited features of the instantly claimed invention, which is the selection of two different salts in a solid aggregation state of an active agent, rather than its function being merely attributed to the selection of excipients such as an enteric coating. In the absence of such proof, the examiner will maintain the enablement rejection of record.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh
Examiner
Art Unit 1618

sjo


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600